

DECISION



**THE COMPTROLLER GENERAL
OF THE UNITED STATES**
WASHINGTON, D.C. 20548

PK-II

FILE: B-214578

DATE: August 10, 1984

MATTER OF: Inventive Packaging Corporation

DIGEST:

1. Allegation that specification requiring non-reversible safety caps for drug prescription bottles is arbitrary and capricious and contrary to Poison Prevention Packaging Act of 1970, 15 U.S.C. § 1471 et seq. (1976) and the implementing regulations is denied since neither the Act nor the regulations mandate a particular type of child-resistant packaging and therefore the contracting agency has the responsibility for drafting specifications as to the type of cap which meets its minimum needs. GAO will not object to the specification since it calls for a type of cap permissible under the Act and regulations and protester has not introduced evidence of a lack of reasonable basis for the specification.
2. An agency need not relax or revise solicitation requirements which reflect its legitimate minimum needs.
3. Protest that specification requiring non-reversible safety caps prevents full and free competition because firms which cannot supply caps of that type are eliminated from competition is denied since propriety of a particular procurement is judged on whether government obtains reasonable prices through adequate competition and not by whether every potential contractor can compete.

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Inventive Packaging Corporation protests that the specification for safety caps for drug prescription bottles in invitation for bids (IFB) No. M1-89-84 issued by the Veterans Administration is contrary to public policy and unduly restricts competition. We deny the protest.

Subsequent to the filing of its protest with our Office, Inventive filed suit against the VA in the United States District Court for the District of Colorado, seeking injunctive and declaratory relief. Inventive Packaging Corporation v. Harry N. Walters, Civil Action No. 84-A-1365. On July 5, 1984, the court issued an order temporarily restraining performance of the contracts awarded under the IFB and requesting an opinion from our Office. The parties have agreed to an extension of the temporary restraining order pending our decision. This decision is in response to the court's request.

The solicitation sought drug prescription bottles with safety caps which are "of the press-lug design or the line-up-the-arrow orientation type, but not reversible." A nonreversible cap is solely a child-resistant closure, while a reversible cap serves a dual purpose: when the cap is turned clockwise it is child-resistant and when it is turned counter-clockwise it is not child-resistant.

Child-resistant closures were initially required by the Poison Prevention Packaging Act of 1970, 15 U.S.C. § 1471 et seq. (1976), which called for the establishment, by regulation, of standards for child-resistant packaging while also allowing non-child-resistant packaging for handicapped or elderly persons and any persons requesting them.

Inventive contends that its reversible safety cap, which is of the press-lug design, complies with the specific language of the Act by providing a means of packaging which can meet both the needs of those who need child-resistant packaging and those who do not. Inventive further states that the Consumer Product Safety Commission (CPSC), which is charged with administering the statute, has studied the use of reversible caps and has not promulgated any rules prohibiting such caps under the Act. It adds that the CPSC has established testing for child-resistant packaging and its caps meet those standards. See 16 C.F.R. § 1700.20 (1983). The protester concludes that it is arbitrary and capricious for the VA to exclude a type of cap which the Act and the CPSC regulations do not prohibit from being supplied to the general public as a child-resistant closure.

Inventive also states that by not permitting reversible caps, the VA eliminated several manufacturers of acceptable items, including itself, from competing for this contract and therefore prevented "full and free competition." See 41 U.S.C. § 253 (1976). It states that competition should be measured both by the number of firms involved and in a qualitative sense. Inventive asserts that although six firms submitted bids in response to this solicitation, the elimination of any firm from bidding prevents full and free competition. As to the quality of competition, Inventive argues that its elimination from competition for this contract decreases cost competition for it was the low bidder by a substantial amount under both this solicitation and the previous solicitation for the same item but both times it was rejected for not complying with the purchase description.

Inventive further contends that competition is improperly limited by not allowing reversible caps since those caps are "only marginally outside the restrictions" of the solicitation. See Federal Procurement Regulations (FPR), 41 C.F.R. § 1-1.307(b) (1983). It maintains there is no greater risk associated with reversible caps than with nonreversible caps and cites as evidence a study which indicates that 14.1 percent of reversible caps found in the home were being used in the non-child-resistant mode, while 15.7 percent of the conventional child-resistant packages were being left open and thus were in effect non-child resistant. It states that the VA, on the other hand, has failed to introduce any evidence demonstrating a greater incidence of accidental child poisoning with reversible caps than with nonreversible and has also ignored the fact that the CPSC has not found any evidence suggesting such a connection. Inventive therefore contends that the restriction of nonreversible caps is not essential.

Inventive adds that the Defense Logistics Agency (DLA) issued a solicitation with a similar purchase description which excluded reversible caps but it modified its requirement to allow acceptance of Inventive's reversible cap after the firm protested that specification.

The VA does not dispute that Inventive's reversible cap meets the requirements of the Act and that the CPSC has not prohibited the use of reversible caps for products requiring child-resistant packaging under the Act, though it notes that CPSC has not actually approved the use of

such caps as child-resistant packaging. See 46 Fed. Reg. 57722 (Nov. 25, 1981).^{1/}

The VA asserts, however, that it has a reasonable basis for restricting the procurement to nonreversible caps. It states that the purpose of this procurement is to meet its annual supply depot requirements from which its medical centers draw quantities needed to fill prescriptions. The VA's pharmacy service fills more than 20 million prescriptions for veterans to take home and 20 million more for mailing to veterans. The VA states that it feels a particularly strong responsibility to assist its patients in protecting their children and family members from the potential danger of these drugs because it dispenses prescriptions containing a 30 to 90 day supply of medication, in contrast to the 5 to 7 day supply typically prescribed in the private sector. Accordingly, the VA requires that nonreversible caps be used for child-resistant packaging, because it believes there is a risk that its personnel would turn a reversible cap the wrong way and mail out or issue prescriptions with the cap in a non-child-resistant position when it is supposed to be in a

^{1/} In 1981, the CPSC staff "recommended that the Commission propose a regulation to prohibit the further use of dual purpose packaging as child-resistant packaging under the [Act]." With the Chairman abstaining, two Commissioners voted for, and two against, the staff's recommendation. Therefore, no regulatory action was initiated concerning dual-purpose closures. According to the Commission's notice of this decision which appeared in the Federal Register:

" . . . packages with dual purpose closures that meet the definition of special packaging in the mode intended to be child-resistant will continue to be in compliance with applicable child-resistant packaging requirements for the substance in that package. However, the split decision does not indicate that the Commission has approved or endorsed dual purpose closures as child-resistant packaging."

46 Fed. Reg., supra.

child-resistant position, thus creating the possibility that children would have easy access to prescription drugs. The VA maintains that this risk is eliminated by requiring nonreversible caps and that this is a reasonable basis for this specification. It adds that despite this requirement there was adequate competition on this solicitation in that six firms--four of whom bid on all items--submitted responsive bids, while six firms submitted responsive bids on the previous procurement with the same specification.

With regard to the protester's first argument, we note that the Act permits the CPSC to establish by regulation standards for "special"--i.e., child-resistant--packaging of household substances, which includes prescription drugs. The CPSC is prohibited by the statute from prescribing specific packaging designs: in the case of prescription drugs, the CPSC's regulations state that containers designed and constructed to meet certain standards are to be regarded as "special packaging" within the meaning of the Act. The standards are expressed in a detailed testing protocol in which panels of young children and of adults are given samples of the packaging and are permitted a limited time in which to open them. If the packaging meets prescribed levels of resisting opening by children, yet accessibility by adults, it qualifies as "special packaging" under the Act.

Inventive states, and the VA does not dispute, that its reversible cap has passed the testing protocol prescribed by the CPSC for "special packaging." The protester maintains that it is arbitrary and capricious, and a "violation" of the Act and the CPSC's implementing regulations, for the VA to exclude Inventive's reversible cap, which is available in the commercial marketplace to consumers who purchase prescription drugs.

As we have indicated above, the CPSC has not prescribed any specific design for special packaging of prescription drugs. The protester's design is but one which has satisfied the testing protocol for special packaging. We assume a pharmacist dispensing prescription drugs to consumers has the discretion to select from among the competing designs of several manufacturers that which in his or her professional judgment best serves the patient's needs. We believe the VA should be permitted to exercise the same discretion unless it is shown that the VA's decision has no reasonable basis.

The contracting agency has the primary responsibility for the determination of the needs of the government and the methods of accommodating such needs. Williams Electric Co., Inc., B-212987 et al., Feb. 27, 1984, 84-1 CPD ¶ 236. Government procurement officials are familiar with the conditions under which supplies, equipment or services have been used in the past, and how they are to be used in the future, and therefore are generally in the best position to know the government's actual needs and consequently are best able to draft appropriate specifications. Memorex Corporation, B-212660, Feb. 7, 1984, 84-1 CPD ¶ 153. Consequently, we will not substitute our judgment for that of the contracting agency absent clear and convincing evidence that the agency's judgment that the specifications reflect the government's minimum needs is in error. Williams Electric Co., Inc., supra.

It is not unreasonable to assume--as the VA has--that if reversible caps are used prescriptions that are intended to be issued or mailed out with the caps in the child-resistant position may erroneously be distributed in the non-child-resistant position, thus, posing a danger to children. This danger is accentuated by the large supply of medication included in each prescription and the very large volume of prescriptions that are dispensed. By not using this type of cap, the risk of such errors occurring is obviously eliminated.

Inventive has not shown that the risk envisioned by the VA with the use of reversible caps does not exist or that the requirement of nonreversible caps is not reasonably related to the elimination of this risk. Inventive merely points out that nonreversible child-resistant caps may be left open by veterans receiving their prescriptions, but that is the decision of the individual veteran. On the basis of the record, it does not appear that the VA's judgment that nonreversible caps reflect its minimum needs was unreasonable. We therefore have no basis to object to the specification.

As to Inventive's assertion that its reversible cap is "only marginally outside the restriction," the question of whether certain requirements in a solicitation are marginal is directly related to an agency's minimum needs determination. A requirement is proper, and need not be revised or relaxed, if it is necessary to satisfy the government's

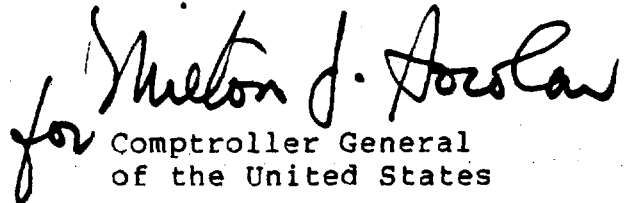
minimum needs. Eastern Marine, Inc., B-213945, March 23, 1984, 84-1 CPD ¶ 343.

As discussed above, we are persuaded that the requirement for nonreversible caps is a legitimate means of reducing the risk of erroneously dispensing prescriptions in non-child-resistant packaging and this is part of the VA's minimum needs. It follows that this requirement need not be relaxed just so Inventive will be able to compete.

Although Inventive contends that competition is limited by this requirement, the propriety of a particular procurement is not judged by whether every potential contractor is included, but rather from the perspective of the government's interest in obtaining reasonable prices through adequate competition. Memorex Corporation, supra. Thus, although Inventive and others may have been eliminated from competition, the record shows that there were six responsive bidders under this solicitation--four of which bid on every item, and we therefore conclude that the VA obtained adequate competition. See Scripto, Inc., B-209450, Nov. 9, 1982, 82-2 CPD ¶ 431. The fact that a firm such as Inventive may submit a lower price for a different item is irrelevant because that product would not be meeting the government's legitimate minimum needs. See Maremount Corporation, 55 Comp. Gen. 1362, (1976), 76-2 CPD ¶ 181.

Finally, the fact that DLA changed its specifications to allow the reversible cap offered by Inventive does not mean that the VA should do likewise. We point out that DLA's justification for its needs are not before us. However, the record in this case provides a reasonable basis for the VA's minimum needs.

The protest is denied.

for 
Comptroller General
of the United States